REMARKS

Claims 14 and 18 are currently pending in this application. Claim 14 has been amended. This amendment is supported by disclosure appearing on page 5 of the application, as filed. Claims 19 and 20 have been cancelled.

Applicants respectfully request reconsideration of the application in view of the above amendments and the following remarks.

Applicants' Response to 35 U.S.C. §112 Rejection

Claims 14 and 18 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner objects to the deletion of eucalyptus from the claims.

With respect to claim 14, this claim is directed to a specific sub-genus of flavors, i.e., fruit flavors. Fruit flavors are described as a specific flavor sub-genus in the original application. For instance, on page 4, the application explains:

> The enhancement and perceived prolongation of fruit flavors is a preferred application of the present invention.... Fruit flavors include but are not limited to, lemon, orange, lime, apricot, grapefruit, banana, cherry, apple, pineapple, grape, strawberry and blends such as tutti fruitti and fruit punch and the like.

Fruit flavors are mentioned as a specific flavor category throughout the specification. Further, a number of the originally filed dependent claims were specifically directed to a fruit flavor (original claims 3, 7, 11 and 16). Accordingly, fruit flavors are fully supported as a flavor sub-genus in the original application. Claim 14, therefore, does not merely exclude eucalyptus. Rather, it is directed to a specific sub-genus of flavors, which is fully supported by the written description. *See* MPEP § 2163.05. The new matter rejection of claim 14, therefore, is improper.

Applicants have cancelled claim 18 herein. Accordingly, the Section 112, first paragraph rejection of claim 18 has been obviated.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the Section 112 rejection.

Applicants' Response to 35 U.S.C. §103 Rejection over Record

Claims 19 and 20 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 5,372, 824 to Record et al. (hereinafter "Record"). Applicants have cancelled claims 19 and 20 herein, and thus, respectfully submit that this rejection has been obviated. Withdrawal of the Section 103 rejection over Record is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Cherukuri

Claims 14 and 18-20 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 5,009,893 to Cherukuri et al. (hereinafter "Cherukuri").

At the outset, claims 19 and 20 have been cancelled herein. Thus, only claims 14 and 18, which are directed to chewing gums, remain in this application. Applicants respectfully submit that Cherukuri fails to render Applicants' claims 14 and 18 obvious, as amended herein.

With respect to claims 14 and 18, the Examiner asserts that Cherukuri discloses the combination of a flavor, such as mint and cherry, and N-ethyl-p-menthane-3-carboxamide in the amounts claimed for use in chewing gums. The Examiner specifically refers to Table V of Cherukuri. According to the Examiner, Cherukuri only differs as to enhancement and the specific flavors.

Applicants have amended independent claim 14 herein to specifically recite the amount of the fruit flavor agent present in the enhanced flavor composition. Amended claim 14 now

requires the fruit flavor agent to be present at about 97.8 to about 99.96% by weight of the enhanced flavoring composition, and N-ethyl-p-menthane-3-carboxamide, a cooling agent commonly referred to as "WS-3", to be present at about 0.04 to about 2.2% by weight of said enhanced flavoring composition. Cherukuri fails to disclose or suggest a chewing gum including an enhanced flavoring composition with a fruit flavor and N-ethyl-p-menthane-3-carboxamide, in these specifically recited amounts. Moreover, there is no appreciation in Cherukuri for using such low amounts of N-ethyl-p-menthane-3-carboxamide to enhance a fruit flavor. Rather, Cherukuri uses N-ethyl-p-menthane-3-carboxamide as a cooling agent, and thus, in much higher amounts.

Cherukuri simply contains a general reference to flavor agents in the description of its invention. In particular, Cherukuri lists "flavoring agents" among optional conventional additives for use in its chewing gums. (Col. 6, lines 18-19). This description does not provide any specific flavors or amounts at which the flavor agents may be used in chewing gum. There is no suggestion in this general description to combine a fruit flavor and N-ethyl-p-menthane-3-carboxamide in Applicants' specifically recited amounts.

Rather, the primary focus of Cherukuri is the combination of menthol and N-substituted-p-menthane carboxamides for cooling purposes. In particular, Cherukuri teaches that N-substituted-p-menthane carboxamides are used in amounts of 30-95% and menthol is used in amounts of 5-70% by weight of this combination. Cherukuri states that "[i]t is critical that the amount of the N-substituted-p-menthane carboxamide compound not be below 30% by weight of the combination, since such low amounts fail to form products that exhibit long-lasting cooling which are not bitter." (Col. 4, lines 26-31). Thus, high amounts of N-ethyl-p-menthane-3-carboxamide, such as 30% or more by weight of its combination, are used in Cherukuri's compositions solely for cooling purposes. Such disclosure fails to suggest the enhancement of a fruit flavor by low amounts of N-ethyl-p-menthane-3-carboxamide.

The only disclosure of a fruit flavor in Cherukuri appears in Example 3, Table V. Example 3 uses cherry flavor. Example 3, however, is directed to confectionery compositions, not chewing gums. Further, the cooling agent in Example 3 is not listed as N-ethyl-p-menthane-3-carboxamide. Table V simply lists the cooling agent as "Cooling Compound 2470". In contrast, all of the remaining examples in Cherukuri specifically state that N-ethyl-p-menthane-3-carboxamide is used, indicating that "Cooling Compound 2470" is not N-ethyl-p-menthane-3-carboxamide.

Only two compositions in Example 3 combine cherry flavor with this unidentifiable cooling agent: confectionery compositions 3 and 4 in Table V. The amount of "Cooling Compound 2470" used in each of these confectionery compositions is 0.010% by weight of the composition. Therefore, the most that this example teaches is preparation of two candy formulations including cherry flavor and 0.010% by weight of an unidentifiable carboxamide cooling agent for purposes of achieving a cooling perception. Such disclosure does not teach or suggest Applicants' claimed chewing gums.

Further, were one of ordinary skill in the art to attempt to modify these confectionery compositions into chewing gums, they would not have achieved Applicants' presently claimed chewing gums. Candy and chewing gum systems are entirely different delivery systems. Candy formulations do not simply convert into comparable chewing gum compositions and in particular the levels of flavoring materials used in candy compositions are not the same as the levels of flavoring materials used in chewing gum compositions. If one of ordinary skill in the art were to attempt to develop chewing gums similar to the confectionery formulations of Cherukuri's Table V, they would have achieved chewing gums that were distinctly different from the presently claimed invention.

As support, Applicants submit herewith a declaration under 37 C.F.R. §1.132 executed by Joan Harvey, a certified flavorist (hereinafter "Harvey Declaration"). The Harvey

Declaration elaborates on the differences in these two delivery systems and how one skilled in the art would not have achieved the presently claimed chewing gums by modifying the confectionery formulations disclosed in Cherukuri's Table V.

By way of background, the declarant describes the differences in confectionery and chewing gum delivery systems, as well as the ensuing difficulties in converting confectionery formulations into chewing gums. In particular, the declarant explains that:

> Confectioneries are water-soluble and designed to be fully consumed, whereas chewing gums are based on a portion that is insoluble and chewed rather than consumed. More specifically, chewing gums include a gum base instead of the candy base listed in Table V. Unlike candy base, gum base is a highly water-insoluble substance, which forms the masticable portion of chewing gums. Gum base includes a number of materials that absorb various components, particularly flavors and actives. These components become entrapped in the gum base, thereby reducing the amount released during chew. Accordingly, the levels of such components often have to be increased when working with chewing gums as compared to confectionery products to achieve comparable effects. In addition to total flavor release concerns, individual components of the flavor release differently and therefore the flavor will taste different when incorporated into chewing gum with the result that the individual flavor components often have to be modified. These are just a few of the difficulties that arise when attempting to convert from a confectionery to a chewing gum delivery system.
>
> (Harvey Declaration; ¶ 7).

These concerns are relevant for the cooling agent N-ethyl-p-menthane-3-carboxamide. (Harvey Declaration, ¶ 8). In particular, the declarant refers to the 1975 publication of N-ethyl-p-menthane-3-carboxamide on the FEMA-GRAS list. The FEMA-GRAS list is the publication of the generally recognized as safe (GRAS) assessment program of the Flavor and Extract Manufacturers Association (FEMA). FEMA-GRAS publishes their assessments of flavor additives and acceptable levels for use. With reference thereto, the declarant states:

> the recognized level of N-ethyl-p-menthane-3-carboxamide for use in hard candy is 100 ppm, whereas the recognized level of N-ethyl-p-menthane-3-carboxamide for use in chewing gum is 1200 ppm. The level recognized for use in chewing gum is 12 times higher than that recognized for use in hard candy.
>
> (Harvey Declaration; ¶ 8).

The declarant also explains that those of ordinary skill in the art customarily consult the FEMA-GRAS list in preparing any consumable product, such as chewing gums, containing a listed component. (Harvey Declaration; ¶ 8). In view of such common practice in the industry, the declarant states:

> I would use these FEMA-GRAS levels in attempting to develop chewing gums including N-ethyl-p-menthane-3-carboxamide. If I were to use N-ethyl-p-menthane-3-carboxamide as the cooling compound referred to in Cherukuri's Table V, then I would begin with the FEMA-GRAS levels in extrapolating confectionery formulations 3 and 4 of Table V into chewing gums.
>
> (Harvey Declaration; ¶ 8).

The declarant continues the description of the extrapolation into chewing gum, stating:

> Based on my experience, at the time of the subject invention, the flavor system in chewing gums typically was used at amounts of about 1-2% by weight of the chewing gum. In view of the FEMA-GRAS levels for N-ethyl-p-menthane-3-carboxamide discussed above, I would use N-ethyl-p-menthane-3-carboxamide in amounts of about 1200 ppm in the chewing gums. 1200 ppm is 0.12% by weight of the chewing gum. The remainder of the flavor composition would include the other flavor components set forth in formulations 3 and 4 of Table V.
>
> (Harvey Declaration; ¶ 9).

As seen in Table V of Cherukuri, cherry flavor and eucalyptus oil make up the remainder of the flavor composition in formulation 3. Cherry flavor, eucalyptus oil and menthol make up the remainder of the flavor composition in formulation 4.

Based thereon, the declarant explains:

> In such an extrapolation into chewing gums, therefore, N-ethyl-p-menthane-3-carboxamide would be present at the amount of 0.12% by weight of the chewing gum. The total flavor composition, of which N-ethyl-p-menthane-3-carboxamide is a part, would be present at amounts of 1-2% by weight of the chewing gum composition. If the minimum total flavor composition amount of 1% were used in the chewing gums, then N-ethyl-p-menthane-3-carboxamide would constitute 12% by weight of the flavor composition itself (0.12% of 1%). If the maximum total flavor composition amount of 2% were used in the chewing gums, then N-ethyl-p-menthane-3-carboxamide would constitute 6% by weight of the flavor composition itself (0.12% of 2%). Therefore, using typical flavor system levels in chewing gum would result in comparable chewing gum products that include anywhere from 6% up to 12% of N-ethyl-p-menthane-3-carboxamide by weight of the flavor composition. In accordance therewith, the remaining flavor components combined would be present at amounts from 88% up to 94% by weight of the flavor composition.

(Harvey Declaration; ¶ 10) (emphasis added).

Therefore, at the time of the invention, if one of ordinary skill in the art had attempted to modify Cherukuri's confectionery formulations 3 and 4 of Table V into chewing gums, they would have incorporated N-ethyl-p-menthane-3-carboxamide at levels of 6-12% by weight of the flavor composition. The remaining flavor components combined would have constituted 88-94% by weight of the flavor composition. These amounts are substantially different from that recited in Applicants' present claims, i.e., about 0.04-2.2% N-ethyl-p-menthane-3-carboxamide and about 97.8-99.96% fruit flavor. As concluded by the declarant:

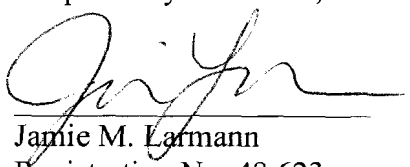
> The amounts of N-ethyl-p-menthane-3-carboxamide in the extrapolated chewing gums described herein, which are based on Cherukuri's Table V confectionery

> compositions, are substantially higher (6-12%) than that recited in these claims (0.04-2.2%). The higher amounts of N-ethyl-p-menthane-3-carboxamide in the extrapolated chewing gums are consistent with the teachings of Cherukuri because N-ethyl-p-menthane-3-carboxamide is being used in its conventional sense, to impart a cooling sensation. This is in contrast to the subject invention, which is using substantially lower levels of N-ethyl-p-menthane-3-carboxamide to enhance a fruit flavor perception, not for its cooling effects.
>
> (Harvey Declaration; ¶ 12).

In view thereof, it is evident that Applicants' presently claimed chewing gums would not have been suggested by the teachings of Cherukuri. If one of ordinary skill in the art had attempted to modify the confectionery teachings of Cherukuri, they would not have arrived at the presently claimed chewing gums. Rather, one skilled in the art would have been led in a different direction by Cherukuri, using higher amounts of N-ethyl-p-menthane-3-carboxamide in chewing gum to achieve a heightened cooling sensation. As such, Applicants' present claims 14 and 18, as amended herein, are patentable over Cherukuri. Applicants respectfully request reconsideration and withdrawal of the Section 103 rejection based thereon.

Favorable action is earnestly solicited. If there are any questions or if additional information is requested, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



Jamie M. Larmann
Registration No. 48,623
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700